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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,485	05/25/2001	Scott D. Feighner	20251P	8604

210 7590 05/02/2006

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,485	FEIGHNER ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,8,12,13,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,4 and 8* is/are allowed.

6)☒ Claim(s) *12,13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Upon further review the finality of the rejection of the last Office action is withdrawn.

2. Amendment filed 2/17/06 has been entered. Claims 8, 13 and 15 have been amended, claims 2-3, 5-7 and 9-11 cancelled. Claims 1, 4, 8, 12-13 and 15-16 are pending.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action (7/18/00).

4. The rejection under 35 U.S.C. 102 is recast in view of the amended claims.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12-13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite because it is not clear which cDNA encodes a polypeptide that functions as a human motilin receptor. The structure of the cDNA nor the polypeptide that functions as a human motilin receptor are provided. The "function" of the receptor is not disclosed. The claims are not defined by a specific function or not structure, therefore the metes and bounds of the claim cannot be determined.

Claims 13 and 15 are rejected for depending on an indefinite base claim and fail to resolve the issues raised above.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-13 and 15 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant ad that the inventors), at the time the application was filed, had possession of the claimed invention. The claims are drawn to cDNA that encodes a polypeptide that functions as a human motilin receptor. The structure of the cDNA nor the polypeptide that functions as a human motilin receptor are provided. The "function" of the receptor is not disclosed. The claims are not defined by a specific function or structure. The claims read on any cDNA that encodes a polypeptide that can be classified as a motilin receptor, not necessarily that of SEQ ID NO:1. The claims are drawn to a genus of polynucleotides that is defined neither by sequence nor by a specific function. The limitation that the cDNA functions as a human motilin receptor and consist of a nucleic acid isolated from a host cell transfected with an expression vector comprising SEQ ID NO: 1 does not provide structure or function.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or

chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. When one is unable to envision the detailed constitution of a complex chemical compound having a particular function, such as a nucleic acid, so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the nucleic acid has been isolated. Thus, claiming all nucleic acids that achieve a result without defining what means will do so is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 , clearly states that Appellant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the ad to recognize that (he or she) invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the

encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird,* 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the isolated cDNA of SEQ ID NO:1 containing the splice variants of SEQ ID NO:3 and 5 (disclosed in the specification), but not the full breadth of the claims meets the written description provision of 35 U.S.C.112, first paragraph. Appellant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1 115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7A. Claims 12-13 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by McKee et. al. (See IDS Genomics, Viol. 46, 426-434, 1997, see prior Office Action).

The claims are drawn to an isolated cDNA encoding a polypeptide that functions as a human motilin receptor wherein the cDNA consists of a nucleic acid isolated from a host cell transfected with an expression vector comprising SEQ ID NO:1. The claims read on any cDNA that encodes a motilin receptor, not necessarily that of SEQ ID NO:1. McKee discloses GPR38 receptor polynucleotide/polypeptide (inherently a motilin receptor), which has 100% query match to the coding region of SEQ ID NO: 1 and comprises SEQ ID NO: 2 (encodes the polypeptide comprising SEQ ID NO: 3) of instant application. McKee further discloses vector containing said polynucleotide and cell containing said vector (see Materials and Methods), thereby meeting the limitation of claims 12-13 and 15, absent evidence to the contrary. The GPR38 is contained in a full-length genomic clone disclosed on page 427, column 1, second paragraph. Although the nucleic acid sequence encoding the GPR38 is not disclosed, the GPR38 clone inherently has the sequence, which encodes the polypeptide that functions as human motilin receptor wherein the cDNA consists of a nucleic acid isolated from a host cell transfected with an expression vector **comprising** SEQ ID NO:1.

Therefore the disclosure of McKee meets the limitations of claims 12-13 and 15 absent evidence to the contrary.

For further clarification it is noted that the rejection of the claims is based on the claims reading on nucleic acid comprising SEQ ID NO:1.

7B. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Harigaya et al (Harigaya et al, Generation of functional clonal cell lines from human bone marrow stroma, Proc. Natl. Acad. Sci. USA, Vol. 82, pp. 3477-3480, May 1985)

Harigaya discloses clonal cell lines from human bone marrow, which were isolated after transfection with recombinant plasmid pSV3gpt, see Abstract and Materials and Methods. The specification discloses applicants splice variants of the motilin receptor were detected in bone marrow tissue. Therefore bone marrow cells inherently contain the motilin receptor of SEQ ID NO:3 and 5. Harigaya discloses a recombinant host cell expressing a human motilin receptor (clonal cell lines from human bone marrow transfected with recombinant plasmid pSV3gpt), wherein the cell lines inherently contain said motilin receptor consisting of an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5, thereby meeting the limitations of claim 16, absent evidence to the contrary.

8. Claims 1, 4 and 8 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi NSB
Art Unit 1646
4/28/06

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER